



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,451	08/21/2003	Joseph L. Bryant	4115-150 CIP DIV	7909

23448 7590 12/13/2006

INTELLECTUAL PROPERTY / TECHNOLOGY LAW
PO BOX 14329
RESEARCH TRIANGLE PARK, NC 27709

EXAMINER

NOBLE, MARCIA STEPHENS

ART UNIT PAPER NUMBER

1632

DATE MAILED: 12/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/645,451

Applicant(s)

BRYANT ET AL.

Examiner

Marcia S. Noble

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.

If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.

Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2006.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
4a) Of the above claim(s) 12-21 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-11 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 21 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SI/08)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

Best Available Copy

DETAILED ACTION

Status of Claims

1. Claims 1-21 are pending. Claims 12-21 are withdrawn as non-elected subject matter. Claims 5 and 11 are amended by Applicant's Response, filed 10/2/2006.

Claims 1-11 are under consideration.

Priority

2. The instant application was not given the effective filing of the prior-filed application, Application No. 09/058,113, filed 4/9/1998, because it failed to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application.

Applicant traversed the denial of priority on the grounds that '113 does provide disclosure of the instant invention and cited the places in the specification of '113 that supported the instant invention of bi-transgenic rat expressing CD4/CCR5 or CD4/CXCR4. However, Applicant's arguments are not found persuasive because the amended claims are not enabled by the instant specification and therefore would not be enabled in the specifications of the priority documents. Therefore, the instant application still does not receive benefit of earlier filing date for '113.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

Art Unit: 1632

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Scope of Enablement

3. Claims 1-11 stands rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a transgenic rat, whose genome comprises a transgene encoding a portion of or a full length CD4 protein that binds to gp120 and CCR5 or CXCR4, if present, and mediates entry of HIV and wherein the CD4 transgene contains a PMBC specific promoter resulting in expression of the CD4 on PMBCs of the transgenic rat and wherein the transgenic rat further comprises a second transgene in its genome encoding a CCR5 or CXCR4 wherein the second transgene comprises a PMBC specific promoter resulting in the expression of CCR5 or CXCR4 on PMBCs, does not reasonably provide enablement for a transgenic rat, whose genome comprises at least one copy of a transgene encoding at least a portion of a CD4 protein sufficient for binding to gp120, wherein CD4 encoded by the transgene is expressed on PMBCs of the transgenic rat and wherein the genome further comprises a transgene encoding for at least a portion of CCR5 or a gene encoding CXCR4 . The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Applicant provided no response to this rejection. Therefore the rejection is maintained.

New Matter

4. Claims 5 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. 37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application".

Amended claim 5 recites, "wherein the at least a portion of a CD4 protein and the at least a portion of CCR5 encoded by the transgene." The specification discloses that a bi-transgenic rat can be made by crossing a CD4 transgenic mouse and a CCR5 transgenic mouse (example 12, page 15). This would imply that the CD4 and the CCR5 are encoded by two different transgenes. However, claim 5 encompasses that both CD4 and CCR5 are encoded by one transgene. The specification provides no literal or figurative support for one transgene encoding both CD4 and CCR5 as is encompassed by the claim.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 5 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recited the limitation "the encoded transgene", which lacked sufficient antecedent basis for this limitation in the claim. Applicant amended the claims to no longer include this recitation, and therefore, this ground of rejection is rendered moot

Claims 5 recited "the encoded transgene is capable of mediating entry of HIV." Applicant amended the claims to recite, "wherein the at least a portion of a CD4 protein and the at least a portion of CCR5 encoded by the transgene", in an attempt to clarify the claim. However, the amendment introduced insufficient antecedent basis with its recitation of "the transgene". Multiple transgenes are present (ie CD4 and CCR5). It is unclear if "the transgene" is meant to be CD4, CCR5, or both, therefore the claim is considered indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-11 stand rejected under 35 U.S.C. 102(e) as being anticipated by Goldsmith et al (US Pat # 6,372,956 B1 4/16/2002; filing date 12/23/1999).

Applicant traversed this rejection on the grounds that Goldsmith et al is not available as prior art because Goldsmith et al was filed on 12/23/1999 and the instant application is entitled to the priority date of 4/9/1998. Applicant's arguments are not

Art Unit: 1632

found persuasive because the priority document does not enable the instant claims, as described above, therefore, the application does not receive the priority date and Goldsmith et al serves as prior art against the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-10 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Browning et al (PNAS 94:14637-14641, 1997).

The instant rejection was based on the grounds that Browning et al teaches bi-transgenic mouse expressing human CD4 and CCR5 that are expressed on lymphocytes and are infected by HIV1 and that it would be obvious to an artisan to

Art Unit: 1632

produce a CD4/CCR5 transgenic rat with a reasonable expectation of success because the methods of producing transgenic mice and rats were developed at the same time, have the same efficiency, can utilize the same vectors, and have often been used interchangeably.

Applicant traversed this rejection on the grounds that the rat genome is considerably different, therefore making the rat would not be obvious. Applicant also argues that as discussed in the specification the transgenic mouse does not closely model the human infection of HIV and that Browning et al confirms this by stating "although transgenic expression of human CD4 and CCR5 permitted entry of HIV into mouse cell, significant infection was prevented...".

These arguments are not found persuasive. The fact the genome of rats and mice have species differences does not preclude being able to produce a transgenic rat. As previously stated producing transgenic mice and rats were developed at the same time, have the same efficiency, can utilize the same vectors, and have often been used interchangeably. Also the fact that the mouse models do not closely model human infection is not relevant because the instant claims do not require that the transgenic rat closely model the human HIV infection. Although is required is that the transgenic animal express CD4 and CCR5 on their PBMC and even if some infection occurs, this would be considered capable of mediating entry of HIV as the claims require. Therefore, since Applicant's arguments are not deemed persuasive, the instant rejection is maintained.

Art Unit: 1632

8. Claims 11 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Sawada et al (J Exp Med 187(9):1439-1449).

Applicant traversed this rejection on the grounds that Sawada et al is not available as prior art because Sawada et al was published on May 1998 and the instant application is entitled to the priority date of 4/9/1998. Applicant's arguments are not found persuasive because the priority document does not enable the instant claims, as described above, therefore, the application does not receive the priority date and Sawada et al serves as prior art against the instant claims.

9. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 1632


the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcia S. Noble whose telephone number is (571) 272-5545. The examiner can normally be reached on M-F 9 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Marcia S. Noble
Art Unit 1632


ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER